



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/833,842	04/10/97	KAESEMEYER	W 97-092-U

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EXAMINER

JONES, D

ART UNIT

PAPER NUMBER

1205

DATE MAILED:

02/05/9

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/833,842

Applicant(s)
Kaesemeyer

Examiner
Dwayne C. Jones

Group Art Unit
1205



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-18 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-18 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Status of Claims

1. Claims 1-18 are pending.
2. Claims 1-18 are rejected.

Drawings

3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.
4. The drawings are objected to because of the reasons set forth by the Office Draftsperson, see enclosed copy of PTO FORM 948. Correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 12-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Morris et al. Morris et al. teach of the composition of a HMG-CoA reductase inhibitor, BMS-180431, with arginine, (see abstract).

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rork et al in view of Griffith. Rork et al. teach the combination of cardiovascular drugs, such as nitroglycerin, and antihypercholesterolemic drugs such as simvastatin, pravastatin and lovastatin, (see column 6, lines 3-5 and 57-59 and column 7, lines 17-19). Rork et al. further teach of the amounts of the drug(s), (see column 7, lines 57-63). Rork et al. is silent to the use arginine with the antihypercholesterolemic drugs.

9. The prior art reference of Griffith teaches it is known in the art that nitroglycerin possesses vasodilating properties and is used to treat cardiovascular disease. Moreover, nitroglycerin is converted in the body to nitric oxide which is the pharmacologically active metabolite. Nitric oxide has been shown to be formed enzymatically from arginine as a normal metabolite which is an important component of endothelium derived relaxing factors (EDRFs), (see column 1, lines 19-30). Since it is established that both arginine and nitroglycerin are the metabolic precursors to the pharmacologically active metabolite, nitric oxide, the skilled artisan would have been motivated to substitute one metabolic precursor of nitric oxide for another, specifically nitroglycerin for arginine. And so, it would have been obvious to the skilled artisan to replace

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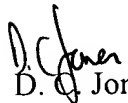
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nitroglycerin for arginine along with the combination of the antihypercholesterolemic drugs of Rork et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Cintins, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


D. C. Jones

January 29, 1998